



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/530,370	07/06/2000	Robert C. Fahey	UCSD1130-1	6677
7590	10/15/2003		EXAMINER	
Lisa A Haile Gray Ware & Friedenrich Suite 1600 4365 Executive Drive San Diego, CA 92121-2189			SWARTZ, RODNEY P	
			ART UNIT	PAPER NUMBER
			1645	
			DATE MAILED: 10/15/2003	
				15

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Advisory Action</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/530,370	FAHEY ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Rodney P. Swartz, Ph.D.	1645

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

THE REPLY FILED 8August2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY [check either a) or b)]**

- a)  The period for reply expires 3 months from the mailing date of the final rejection.
- b)  The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.  
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.  A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2.  The proposed amendment(s) will not be entered because:
  - (a)  they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b)  they raise the issue of new matter (see Note below);
  - (c)  they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d)  they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_.

3.  Applicant's reply has overcome the following rejection(s): see Detailed Action.
4.  Newly proposed or amended claim(s) \_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5.  The a) affidavit, b) exhibit, or c) request for reconsideration has been considered but does NOT place the application in condition for allowance because: \_\_\_\_\_.
6.  The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7.  For purposes of Appeal, the proposed amendment(s) a) will not be entered or b) will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: none.

Claim(s) objected to: none.

Claim(s) rejected: 1-3,5-7,9-11,40,42,48-50.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8.  The proposed drawing correction filed on \_\_\_\_ is a) approved or b) disapproved by the Examiner.
9.  Note the attached Information Disclosure Statement(s) ( PTO-1449) Paper No(s). \_\_\_\_\_.
10.  Other: \_\_\_\_\_.

**DETAILED ACTION**

1. Applicants' Response to Final Office Action, received 8August2003, paper#14, is acknowledged. Claim 8 has been canceled without prejudice. Claims 1, 5, 6, 7, 9, 40, 42, 48, and 50 have been amended.
2. Claims 1-3, 5-7, 9-11, 40, 42, and 48-50 are pending and under consideration.

**Rejections Moot/Withdrawn**

3. The rejection of claims 9-11 under 35 U.S.C. 101 non-statutory subject matter, is withdrawn in light of the amendment of claim 9.
4. The rejection of claim 8 under 35 U.S.C. 112, first paragraph, scope of enablement for a method of detecting a member of the taxa actinomycetes comprising detecting reaction of a thiol-selective reagent with a thiol, is moot in light of the cancellation of the claim.

**Rejections Maintained**

5. The rejection of claims 1-3, 5-7, and 48-50 under 35 U.S.C. 112, first paragraph, scope of enablement for a method of detecting a member of the taxa actinomycetes comprising detecting reaction of a thiol-selective reagent with a thiol, is maintained for reasons of record.

Applicants argue that the claim amendments deleted "thiol-containing mycothiol component" from the claims and therefore they will address the enablement for specific binding of an antibody to a mycothiol derivative. Applicants disagree with the examiner's position that the specification teaches only one polyclonal antibody that binds to mycothiol and not to its carrier proteins and also does not bind to very specific derivatives. Applicants argue that the examples set forth that the antibody does specifically bind a mycothiol derivative.

The examiner has considered applicants arguments, but does not find them persuasive for the reasons set forth in the prior Office Actions. The scope of the instant claims

encompasses any antibody which “specifically” binds to a mycothiol derivative. However, the examples in the specification do not appear to indicate such “specificity”. The claims make no restriction on the amount of binding, just that the antibody binds “specifically” to the mycothiol derivative. The examples and applicants’ argument indicate that the antibody does bind to multiple moieties, just that the antibody appears to bind more to mycothiol derivative. Without any recitation in the claims of threshold levels of binding, any binding would be detected, whether it is to the specific mycothiol derivative or not.

6. The rejection of claims 5, 10, 40, and 42 under 35 U.S.C. 112, first paragraph, written description, is maintained for reasons of record.

Applicants argue that one of skill in the art, at the time of filing of the claimed invention, would have been able to practice the claimed methods utilizing monoclonal antibodies utilizing the polyclonal examples in combination with well known methods of monoclonal antibody preparation.

The examiner has considered applicants’ argument, but does not find it persuasive. The instant rejection is not an enablement rejection, but a written description rejection. While production of monoclonal antibodies can be performed given the well known methods in the art at the time of filing, the instant specification does not provide sufficient information to indicate that applicants actually had possession of any monoclonal antibodies with the required activity. For instance, the specification does not teach which epitopes(s) instill specificity or that the polyclonal antibodies actually comprise any antibody with the specificity which is required for the claimed invention. Without this information, the search for a possible monoclonal antibody merely constitutes an invitation to experiment, and does not convey that the applicants had in their possession any of the claimed monoclonal antibodies.

**Rejection Necessitated by Amendment**

**Claim Rejections - 35 USC § 112**

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 9-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polyclonal antibody which binds to mycothiol, does not reasonably provide enablement for an antibody which binds "specifically" to a maleimidyl derivative of mycothiol. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The instant claims are drawn to an antibody, polyclonal or monoclonal, which binds specifically to a maleimidyl derivative of mycothiol.

The instant specification teaches a polyclonal antibody which binds to not only a maleimidyl derivative of mycothiol, but also to mycothiol without inositol. While the level of binding of the polyclonal antibody to mycothiol without inositol is less than the binding to a maleimidyl derivative of mycothiol, nevertheless there is binding, which indicates a lack of specificity for the scope of the instant claims.

Thus, the newly amended claims constitute merely an invitation to experiment without a reasonable expectation of success in producing an antibody with the claimed specificity.

**Conclusion**

9. No claims are allowed.

10. Applicant's amendment necessitated the new grounds of rejection presented in this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., whose telephone number is (703) 308-4244. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (703)308-3909. The facsimile telephone number for the Art Unit Group is (703) 872-9306

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-2035.

*Rodney P. Swartz*  
RODNEY P SWARTZ, PH.D.  
PRIMARY EXAMINER  
Art Unit 1645

October 14, 2003